

translation through commercialization. **METHODS/STUDY POPULATION:** The diverse, interdisciplinary team of investigators involved in this project span 9 CTSA Hubs, including UAB, Rockefeller, UC Denver, HMC-Penn State, UMass, UC Davis, Emory/Georgia Tech, Miami and Michigan. This team was funded by NCATS in 2015–2016 to participate in the CTSA I-Corps Train-The-Trainer Program in conjunction with the NIH-SBIR/STTR I-Corps national program. The goals were to observe the curriculum, interact with and learn from the NSF National Teaching Team and begin implementation of similar programs at our home institutions. Our I-Corps@NCATS team has been holding monthly, and more recently weekly, conference calls to discuss our experiences implementing local programs and to develop a strategy for expanding CTSA offerings that include innovation and entrepreneurship. Our experience revealed several challenges with the existing NSF/NIH I-Corps program offerings: (1) there is no standard curriculum tailored to academic clinical and translational research and biomedical innovations in the life sciences, and (2) the training process to certify instructors in the I-Corps methodology is a much more rigorous and structured process than just observing an I-Corps program (eg, requires mentored training with a national NSF I-Corps trainer). Our team is proposing to address these gaps by taking best practices from NSF I-Corps and adapting the program to create the I-Corps@NCATS Program, tailored to meet the needs of researchers and clinicians in academic medical centers. **RESULTS/ANTICIPATED RESULTS:** There are 3 primary anticipated results of our project. First, develop a uniform curriculum for the I-Corps@NCATS Program using the National Teaching Team of experts from the NIH's SBIR I-Corps program. Second, build the I-Corps@NCATS network capacity through a regional Train-The-Trainer Program. Third, develop a set of common metrics to evaluate the effectiveness and impact of the I-Corps@NCATS Program across the community of CTSA Hubs and their respective collaborative networks. **DISCUSSION/SIGNIFICANCE OF IMPACT:** Over the past 10 years, CTSA Hubs have accelerated science by creating/supporting programs that provide research infrastructure, informatics, pilot funding, education/training, and research navigator services to investigators. These investments help to ensure that we are “doing science right” using the best practices in clinical research. Even so, it is equally important to make investments to ensure that we are “doing the right science.” Are our investigators tackling research problems that our stakeholders, patients, and communities want and need, to make sure that our investments in science have real-world impact? In order to accelerate discoveries toward better health, scientists need to have a better way to understand the needs, wants and desires of the people for whom their research will serve, and how to overcome key obstacles along the path of innovation and commercialization. To fill this gap, we propose that the CTSA Hubs should include in their portfolio of activities a hands-on, lean startup program tailored after the highly successful NSF Innovation Corps (I-Corps) program. We hypothesize that by adapting the NSF I-Corps program to create an I-Corps@NCATS program tailored to medical research, we will better prepare our scientists and engineers to extend their focus beyond the laboratory and broaden the impact of their research. Investigators trained through I-Corps@NCATS are expected to be able to produce more innovative ideas, take a more informed perspective about how to evaluate the clinical and commercial impact of an idea, and quickly prototype and test new solutions in clinical settings.

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### Opportunities and challenges for precision medicine and biomarkers: A regulatory science case study

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**OBJECTIVES/SPECIFIC AIMS:** To develop a regulatory science case study as an educational resource to inform the regulatory science considerations in medical product development for a range of scientific priority areas and emerging technologies. **METHODS/STUDY POPULATION:** Precision medicine represents one of the major regulatory science priority areas and the use of biomarkers holds promise for predicting the response to individual treatment strategies. Although progress has been made toward developing biomarkers, the development and validation of clinically useful biomarkers has presented significant regulatory science challenges, including the utilization of biomarkers in predicting responses to different cancer therapies. This case study reviews the technical, regulatory, and policy issues related to the development and use of lung cancer drugs Opdivo<sup>®</sup> and Keytruda<sup>®</sup> and an understanding of the codevelopment and utilization of their associated biomarkers. **RESULTS/ANTICIPATED RESULTS:** A detailed instructor guide with extensive resources such as diagrams and timelines will accompany the case study and will be used to highlight the development and approval process of 2 competing drugs and their associated biomarkers. The resources will provide a better understanding of their progression through the FDA regulatory process and opportunities and challenges for their use. **DISCUSSION/SIGNIFICANCE OF**

**IMPACT:** Building on the case study framework we have developed, the detailed timelines and a collection of available resources, an extensive and modular case study will be finalized and made available to academic institutions, industry, regulatory agencies, and the public. The full case study and links to a series of resources will be disseminated as a standalone resource for integration into courses or programs interested in learning about specific regulatory science needs and opportunities to enhance medical product development and approval.

## DIGITAL HEALTH & SOCIAL MEDIA

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### Television viewing: Associations with eating behavior and cravings in healthy, non-obese young adults

Amanda E. Staiano, Corby K. Martin, Jennifer C. Rood and Peter T. Katzmarzyk

**OBJECTIVES/SPECIFIC AIMS:** The majority of obese adults do not become obese until adulthood. Although adults spend the equivalent of a 40-hour work week in front of the television (TV), there are mixed data on whether the sedentary behavior of TV viewing is linked with weight gain during adulthood. The purpose of this study was to examine the associations among sedentary behavior, measured as TV viewing and TV in the bedroom, with eating behavior, eating attitudes and cravings, fat gain, and blood pressure in healthy young adults over a 2-year period. **METHODS/STUDY POPULATION:** The sample included 73 healthy, nonobese adults (56% women, 80% white) who were  $26.8 \pm 4.5$  years of age with a body mass index of  $22.9 \pm 2.4 \text{ kg/m}^2$ . Participants completed clinic visits at baseline and 2-years later (Year 2) which assessed weight, height, blood pressure, waist circumference, and total body fat measured by dual energy X-ray absorptiometry. A food frequency questionnaire was used to estimate dietary intake, and the eating inventory was used to assess dietary restraint, disinhibition, and hunger. At baseline, participants self-reported TV habits including number of hours/week of watching TV (including cable, VCR, DVD) and presence of a TV in the bedroom. For the analysis, participants were stratified by quartiles of TV viewing time. *T* tests were used to examine the association between TV viewing and bedroom TV. Linear regression models were used to examine the association between TV viewing and each anthropometric and body composition measure and change over the 2-year period, as well as with the dietary constructs. Models controlled for age, sex, and baseline body fat. Separate models were used to investigate the associations between bedroom TV and the same dependent variables. **RESULTS/ANTICIPATED RESULTS:** Participants reported an average of  $13.3 \pm 10.8$  hours/week of TV viewing, with 33.3% reporting a TV in the bedroom. There were no differences in age, sex, or race among the quartiles of TV viewing or between those who did and did not have a bedroom TV. Adults with a bedroom TV did not differ in hours/week of TV viewing compared with those without a bedroom TV. Amount of TV viewing was associated with higher systolic blood pressure at baseline ( $p = 0.05$ ) but with no other anthropometric or body composition indices nor with change in body composition over the 2-year period. Adults with a bedroom TV reported higher craving for sweets at baseline ( $p = 0.03$ ). Amount of TV viewing was related to lower consumption of vegetables ( $p = 0.04$ ) and fruit or fruit juice ( $p = 0.03$ ) at Year 2, but there was no association with total calorie consumption. TV viewing and bedroom TV were not related to dietary restraint, disinhibition, or hunger at either time point. **DISCUSSION/SIGNIFICANCE OF IMPACT:** Adults who watched more TV consumed fewer fruits and vegetables, and those with a TV in the bedroom reported higher craving for sweets. Though there were no observed relationships between TV habits and body composition change, the associations with cravings and food consumption warrant further exploration. Querying young adults' TV and media use habits in clinical settings may alert physicians to those at risk of developing poor dietary habits.

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### What factors explain failure to meet clinical recommendations for preschool children's screen-time?

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**OBJECTIVES/SPECIFIC AIMS:** The American Academy of Pediatrics (AAP) recommends that preschool-aged children spend no more than 2 hours/day